

PSJ17 Exh 38

# ACTIQ MARKETING 2001

**Andy Pyfer**  
**February 2001**  
**National Sales Meeting**

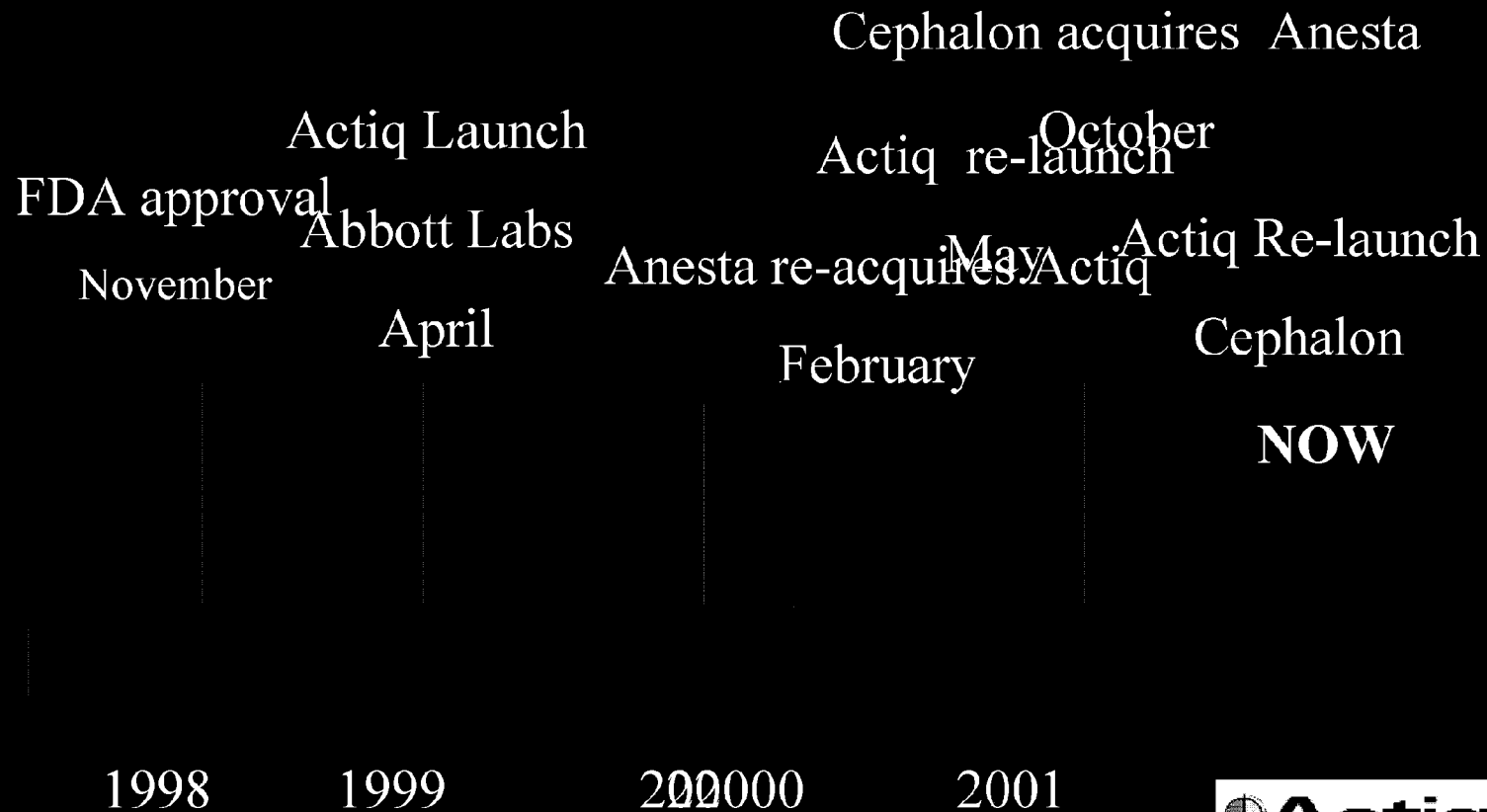


# Actiq Marketing Overview: Key Topics

- I. Actiq History
- II. Opioid Market Review
- III. Actiq Sales Review/Analysis
- IV. Key Issues, Strategies and Tactics
- V. Keys to Success



# I. History of Actiq



## II. Opioid Market Review



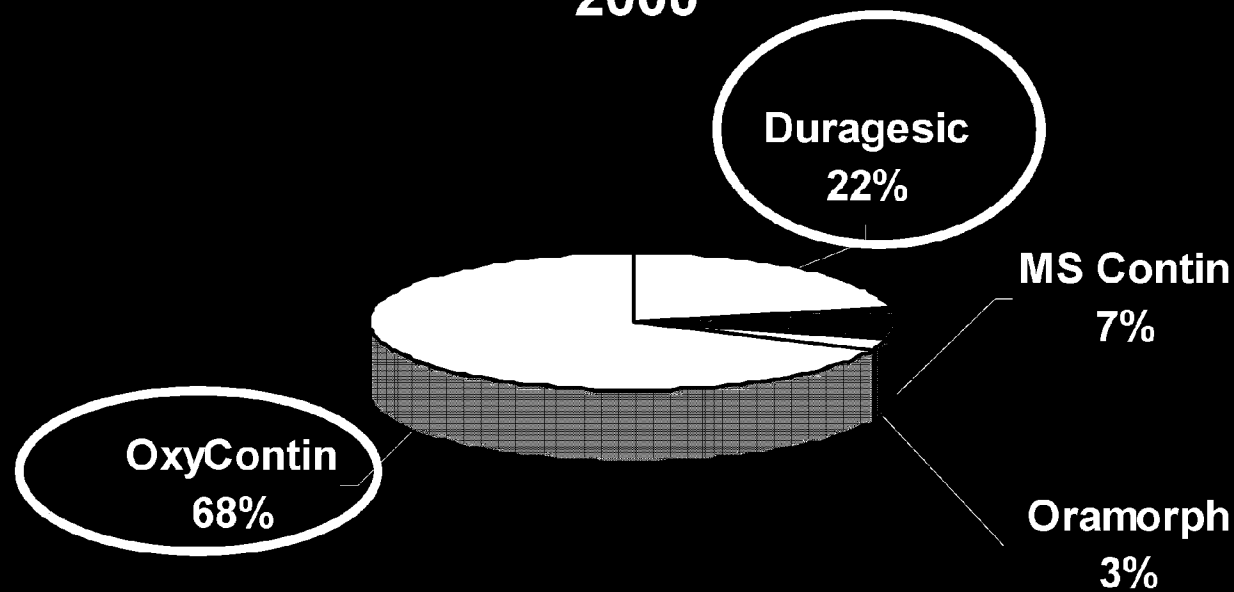
# Long Acting Opioids

<u>Long Acting Opioid</u>	<u>Generic</u>	<u>Company</u>
<b>Duragesic</b>	<b>transdermal fentanyl</b>	<b>Janssen</b>
<b>Oxycontin</b>	<b>oxycodone</b>	<b>Purdue</b>
<b>MS Contin</b>	<b>morphine</b>	<b>Purdue</b>
<b>Oramorph</b>	<b>morphine</b>	<b>Roxane</b>
<b>Kadian</b>	<b>morphine</b>	<b>Faulding</b>



# Long Acting Opioids

## Long Acting Opioid Retail TRx Count 2000



**Actiq**<sup>®</sup>  
(oral transmucosal  
fentanyl citrate)

# Short Acting Opioids

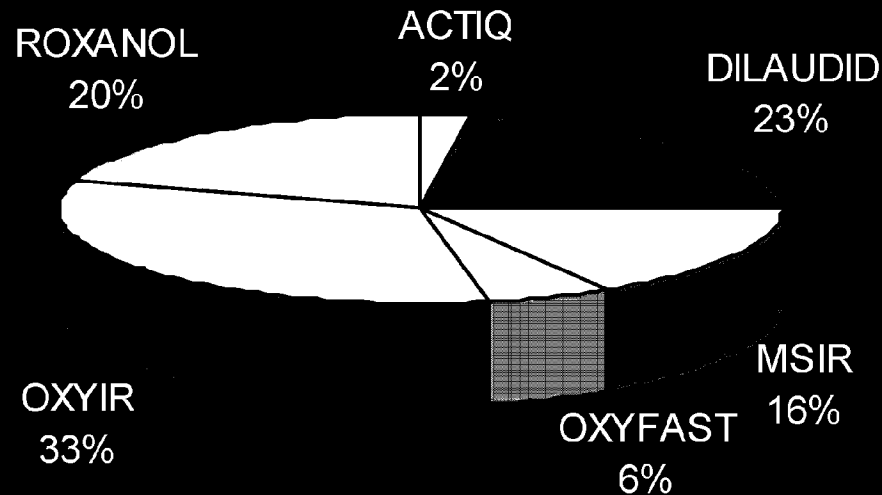
<u>Short Acting Opioid</u>	<u>Generic</u>	<u>Company</u>
<b>Actiq</b>	<b>transmucosal fentanyl</b>	<b>Cephalon</b>
<b>OxyIR</b>	<b>oxycodone</b>	<b>Purdue</b>
<b>Oxyfast</b>	<b>oxycodone</b>	<b>Purdue</b>
<b>MSIR</b>	<b>morphine</b>	<b>Purdue</b>
<b>Roxanol</b>	<b>morphine</b>	<b>Roxane</b>
<b>Dilaudid</b>	<b>hydromorphone</b>	<b>Knoll</b>





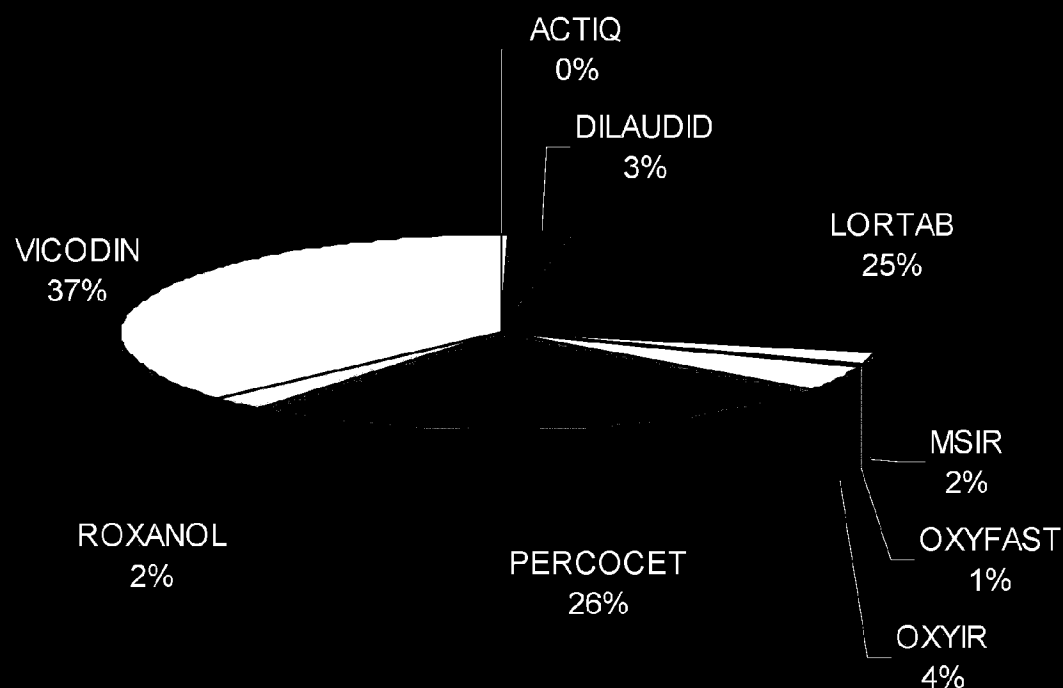
# Short Acting Opioids

## Pure Short Acting Opioid Retail TRx Count 2000



# Short Acting Opioids

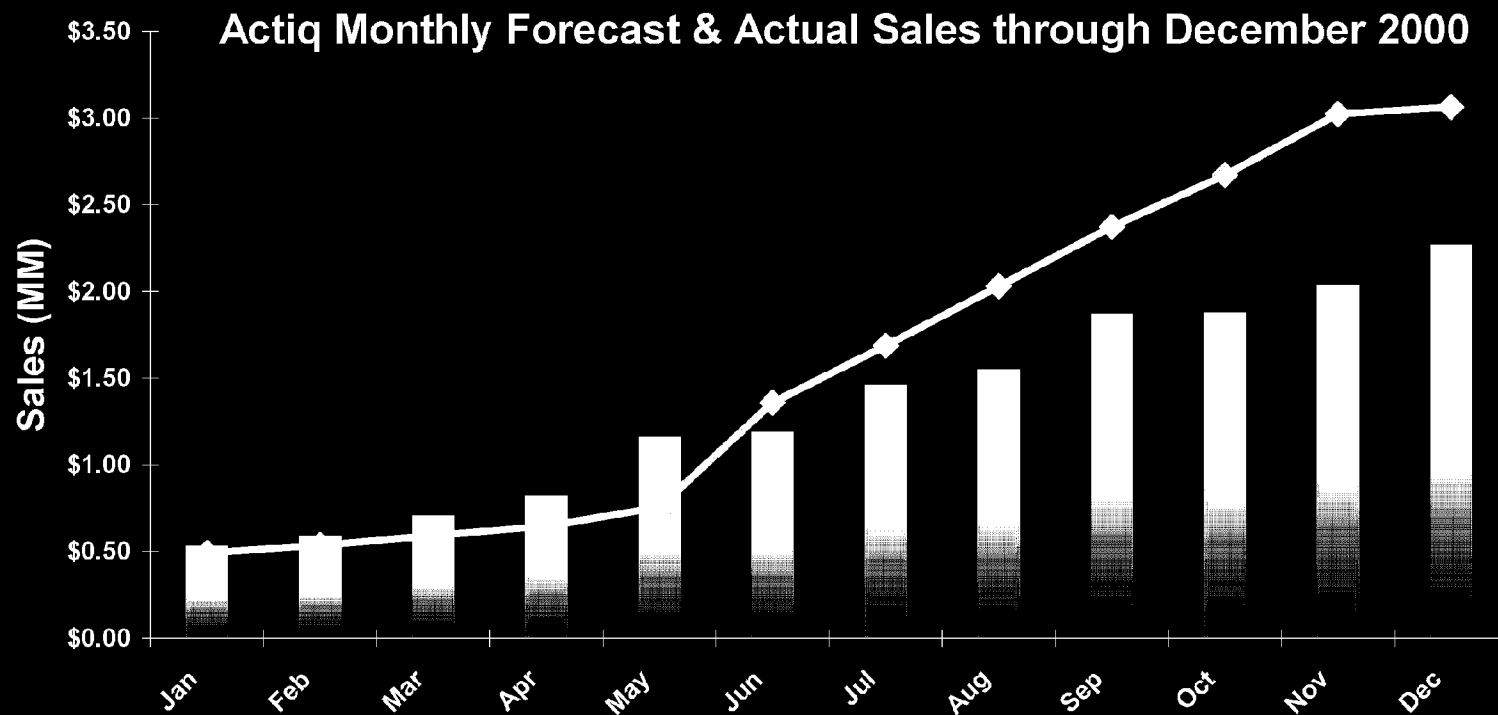
## Short Acting Opioid Retail TRx Count 2000



# III. Actiq Sales Review/Analysis

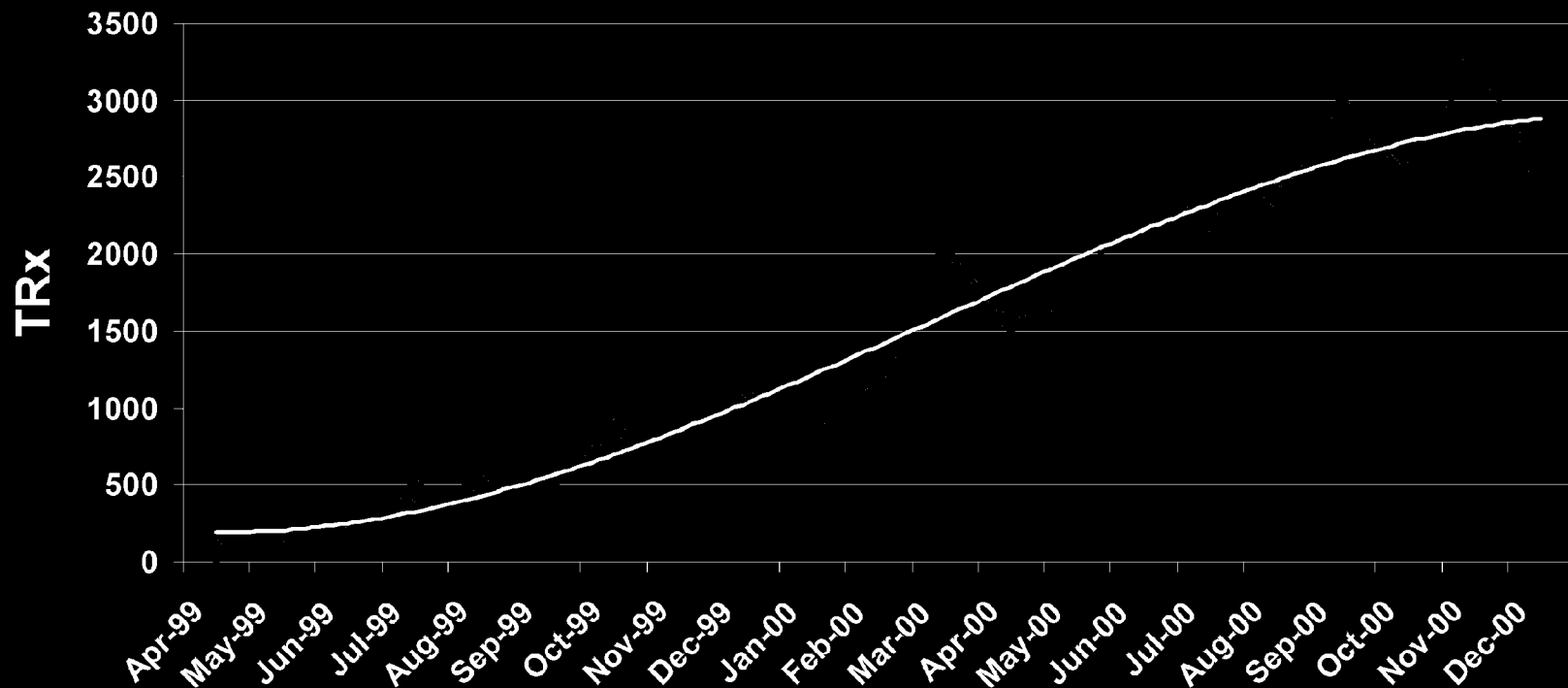


# Actiq Monthly Sales



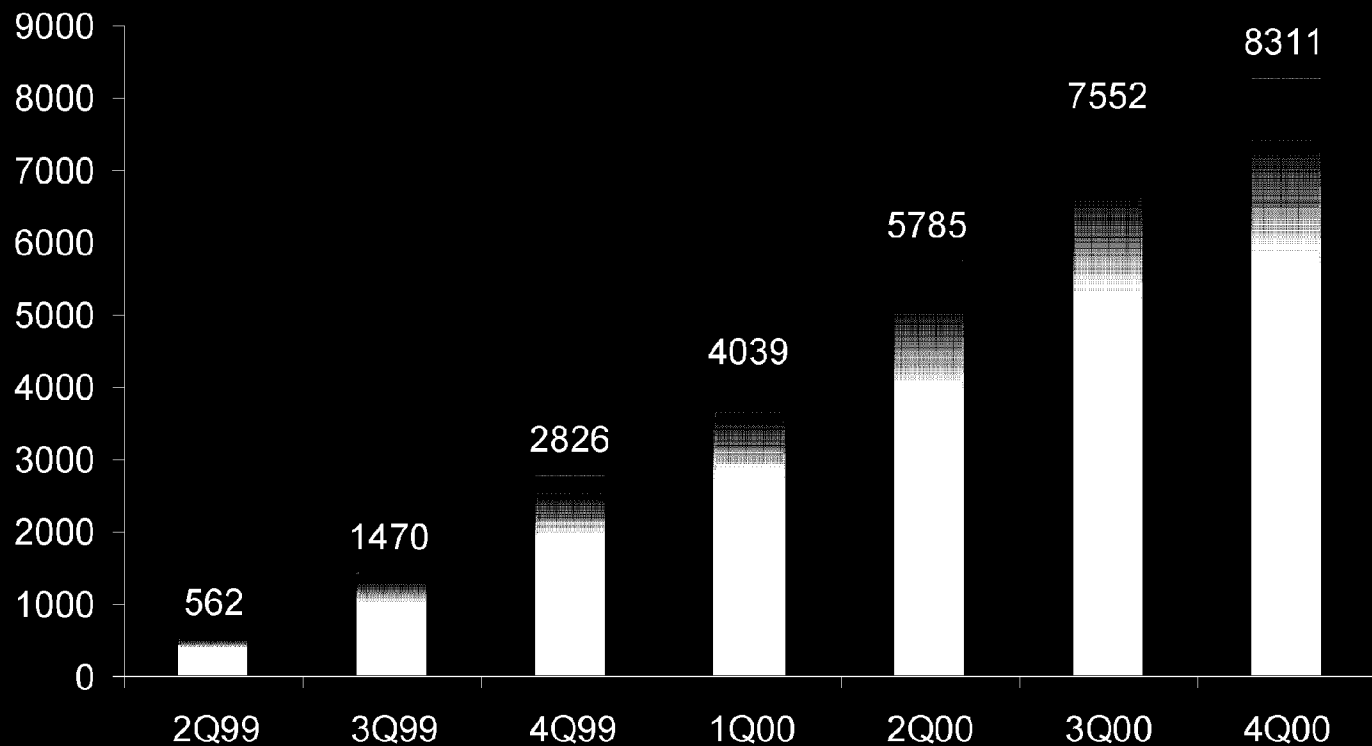
**Actiq<sup>®</sup>**  
(oral transmucosal  
fentanyl citrate)

# Actiq Monthly NPA TRx

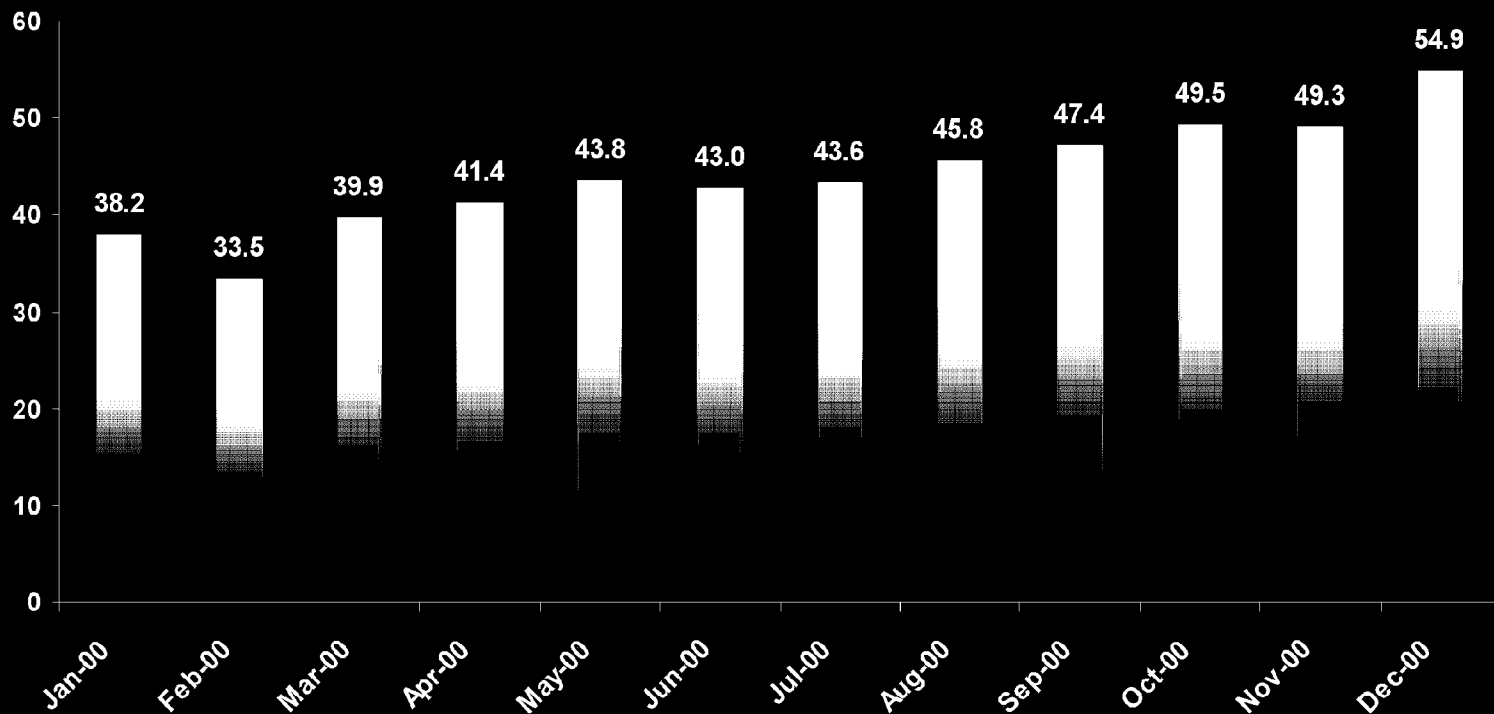


**Actiq**<sup>®</sup>  
(oral transmucosal  
fentanyl citrate)

# Actiq Quarterly TRx

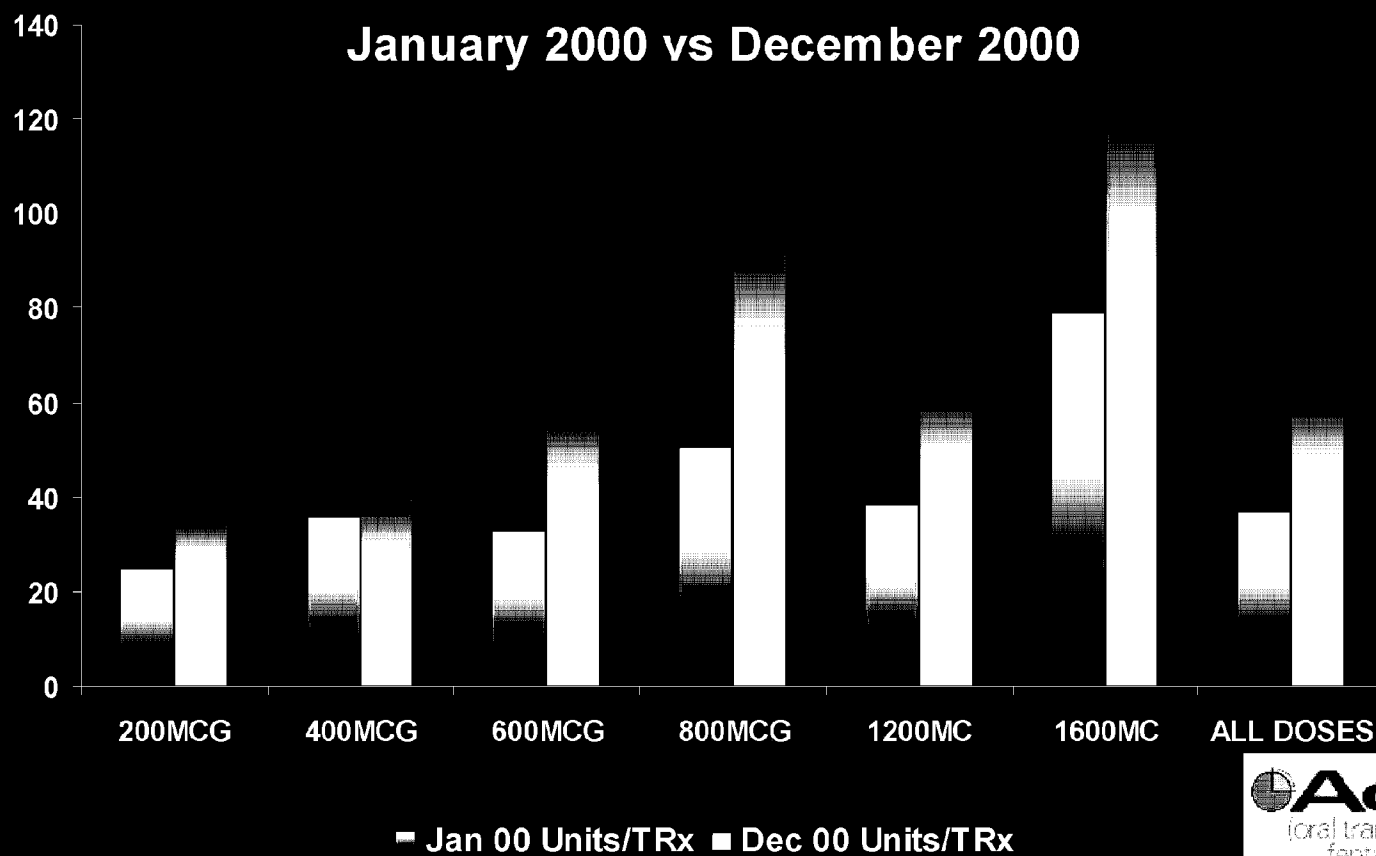


# Actiq Units / Prescription



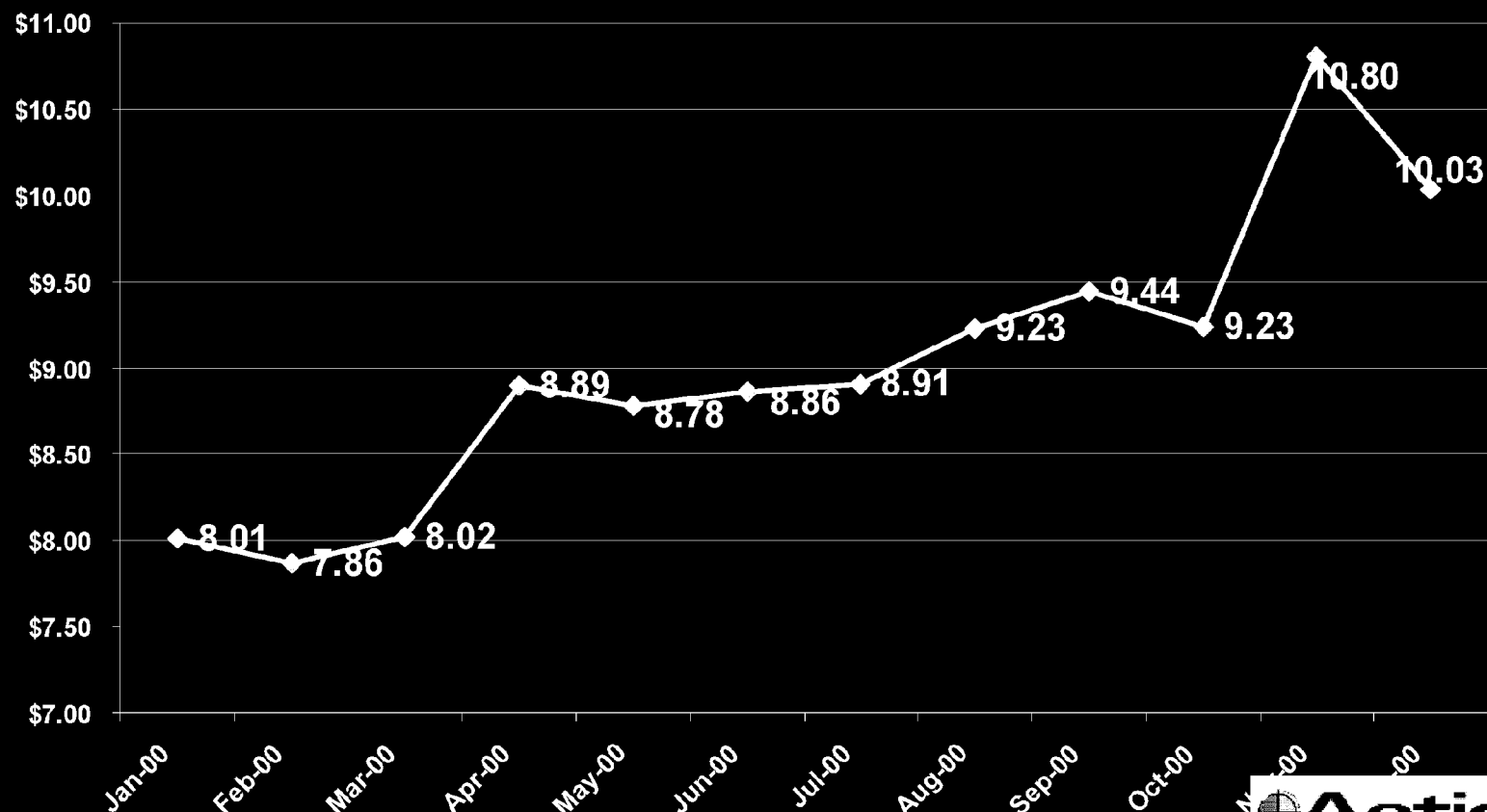
**Actiq**<sup>®</sup>  
(oral transmucosal  
fentanyl citrate)

# Actiq Prescription Size by Strength





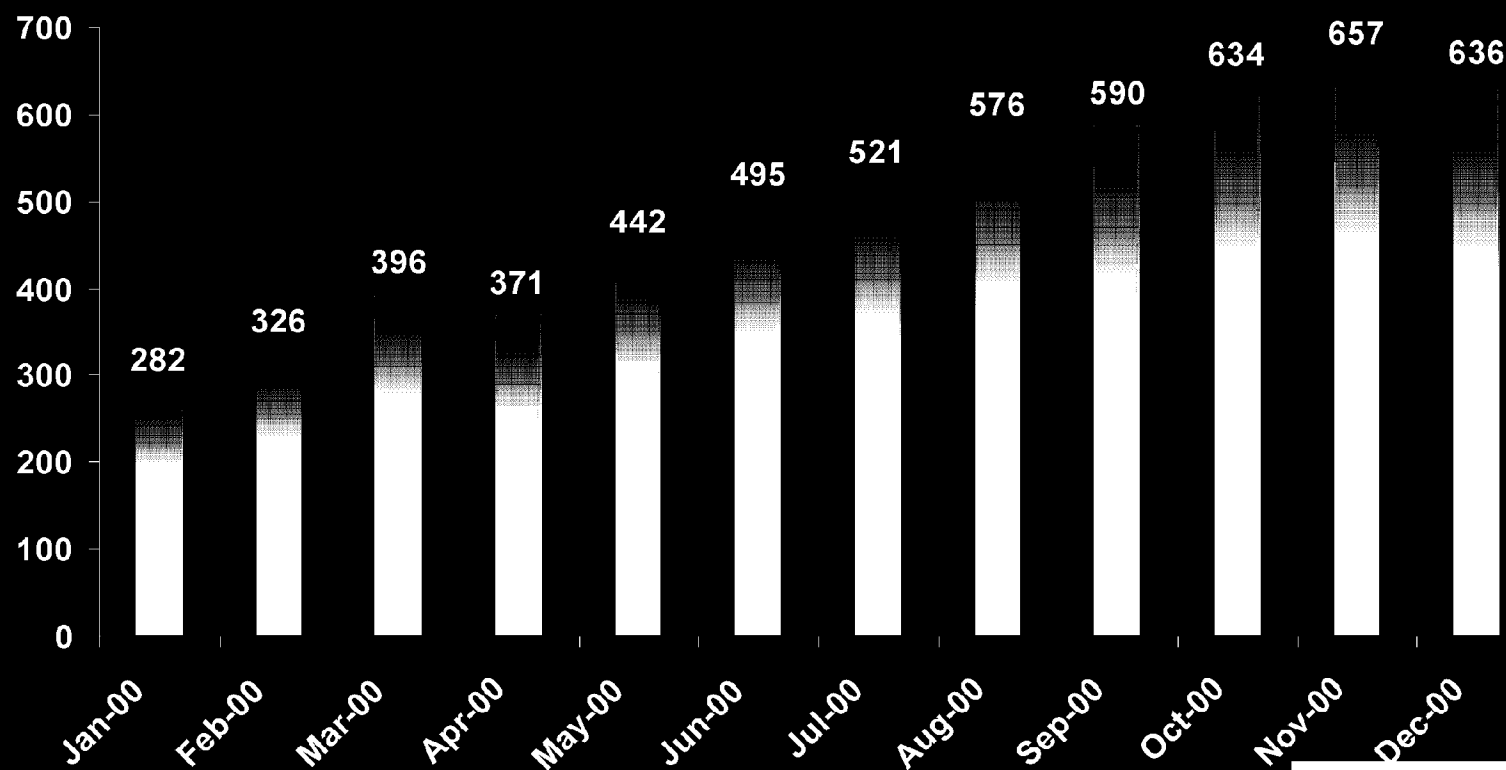
# Factory Average Net Selling Price



**Actiq**<sup>®</sup>  
(oral transmucosal  
fentanyl citrate)

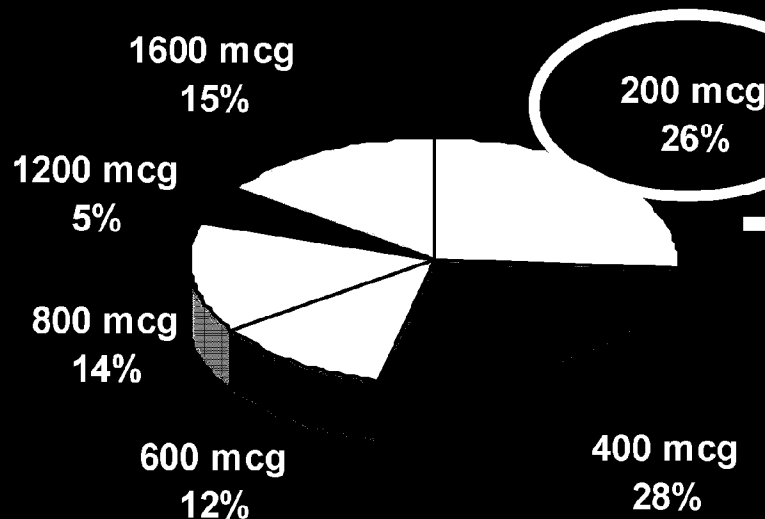
# Actiq Prescriber Analysis

## Xponent – Monthly Prescribers

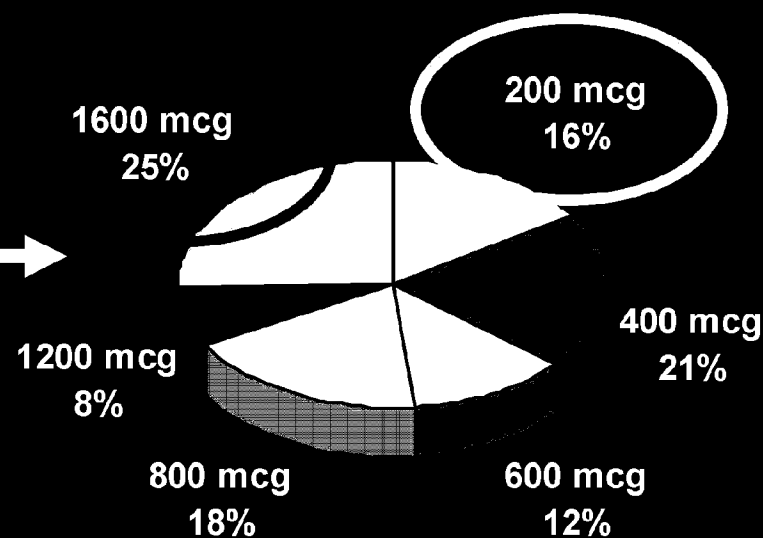


# Percent Units by Strength

January 2000 Xponent



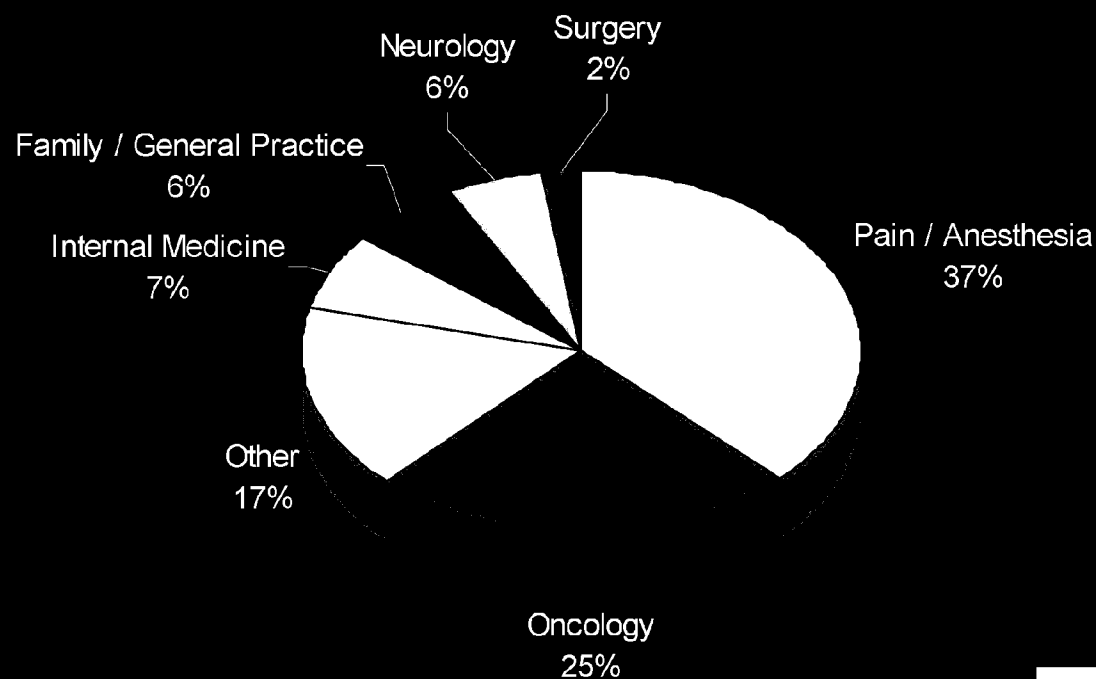
December 2000 Xponent



**Actiq<sup>®</sup>**  
(oral transmucosal  
fentanyl citrate)

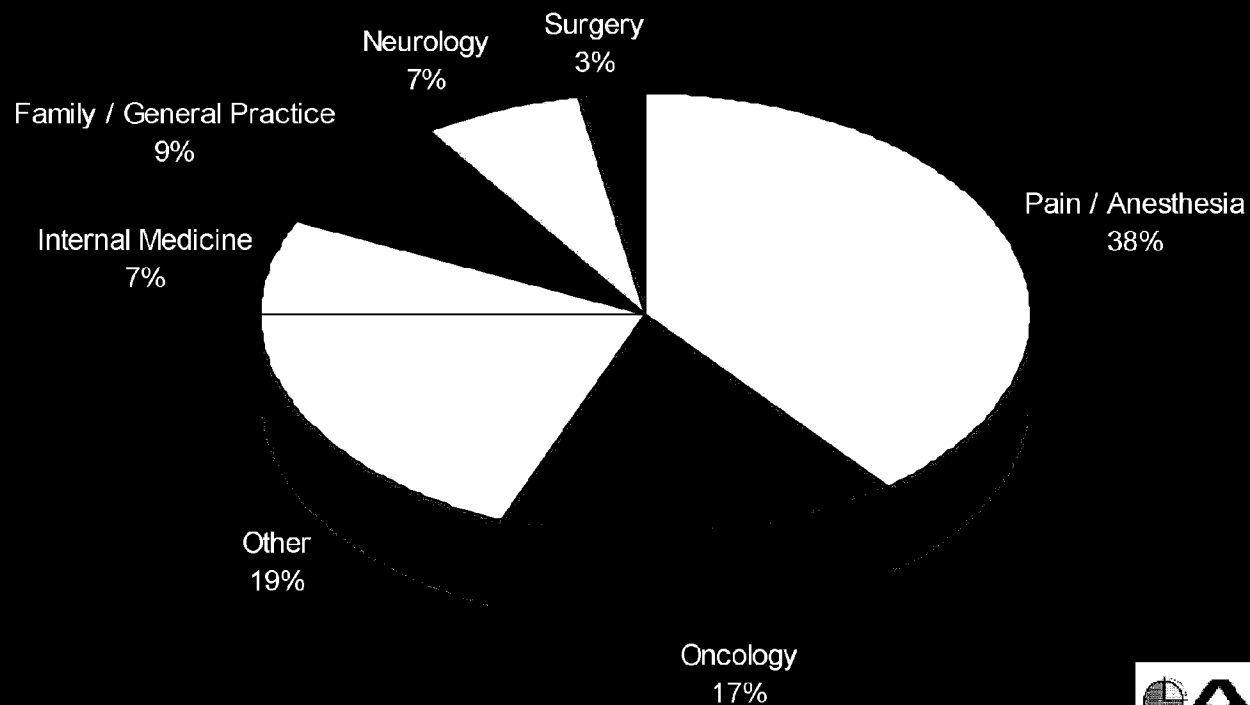
# Actiq Prescriber Analysis

## Xponent YTD TRx by Specialty



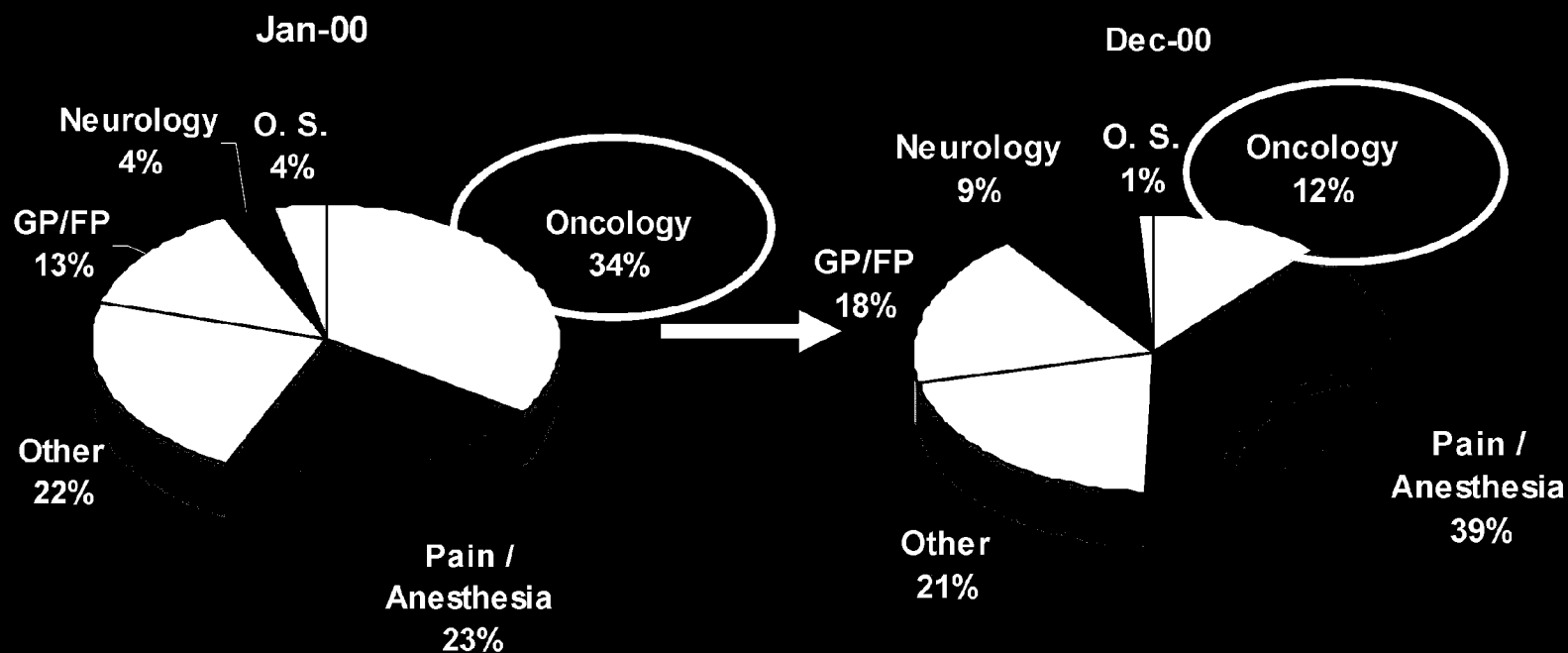
# Actiq Prescriber Analysis

## Xponent – Total Units YTD by Specialty



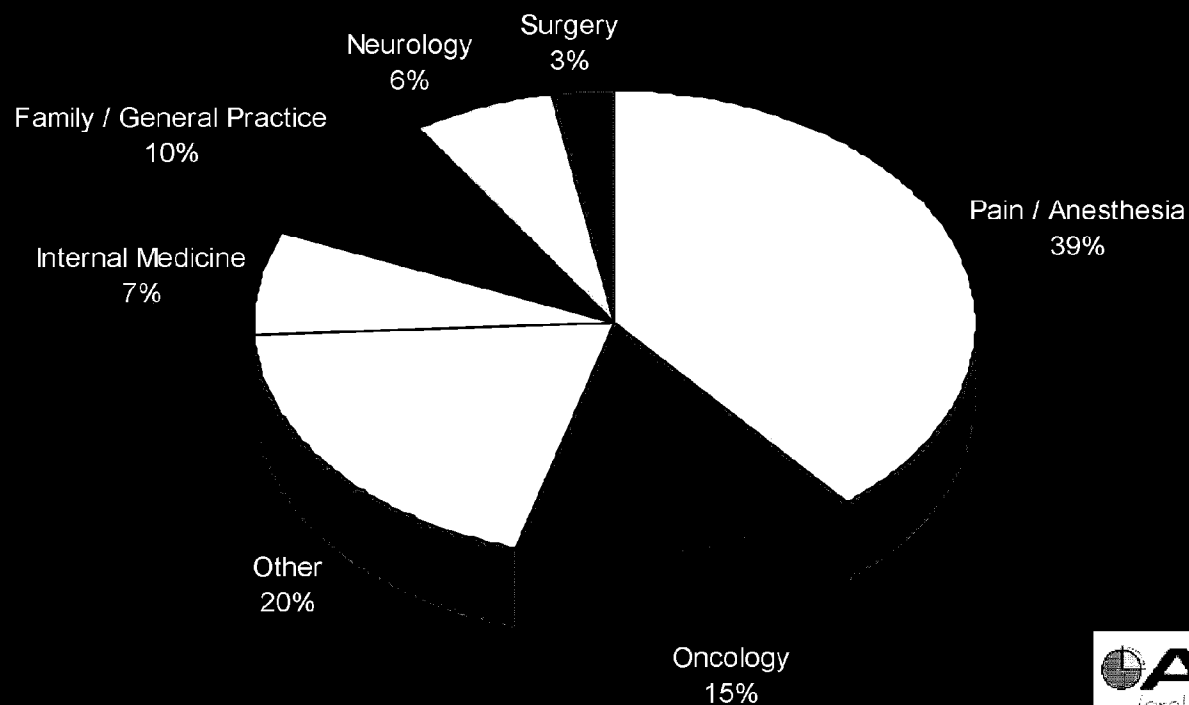
# Actiq Prescriber Analysis

## Xponent - % Units by Specialty

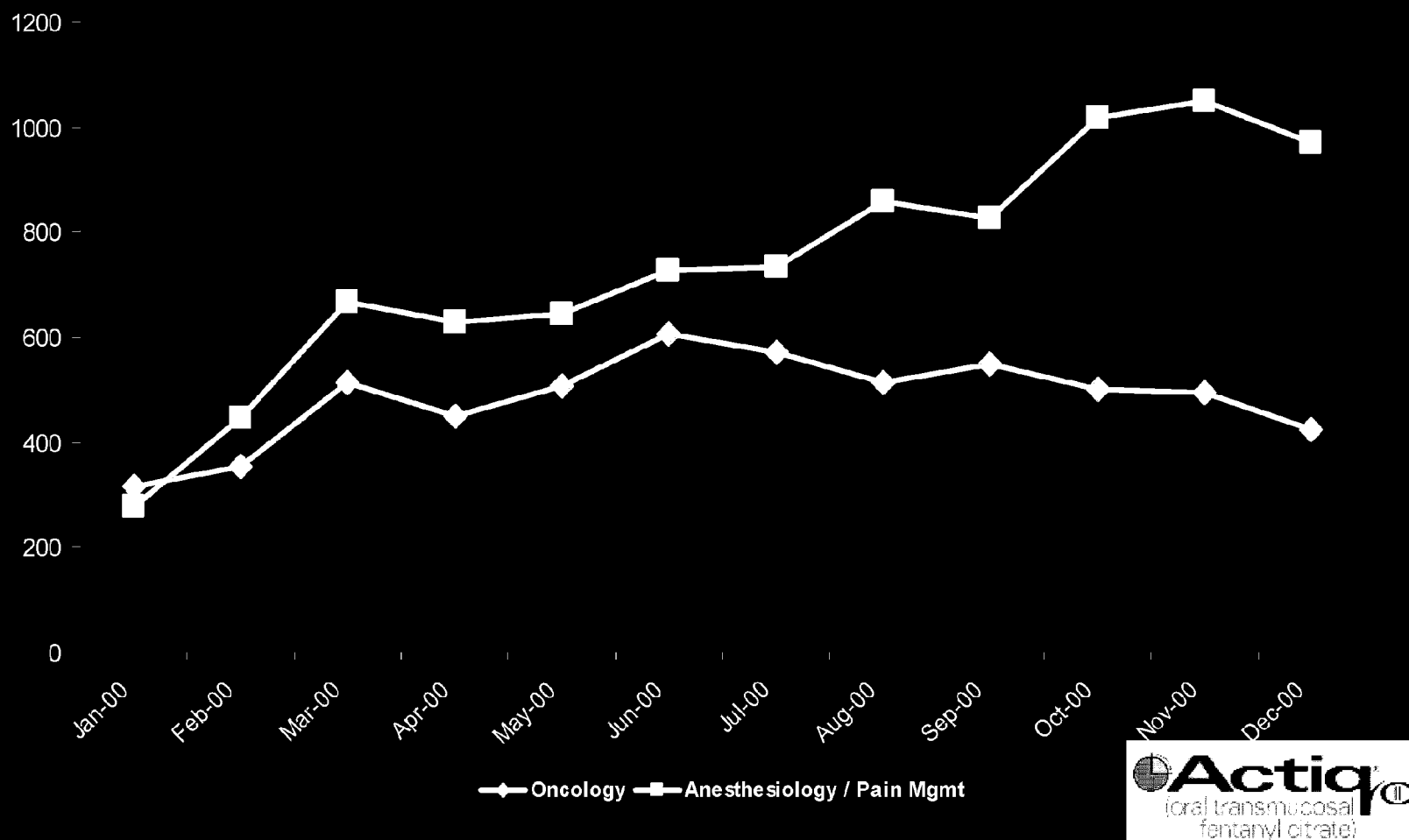


# Actiq Prescriber Analysis

## Xponent – Total Sales YTD by Specialty

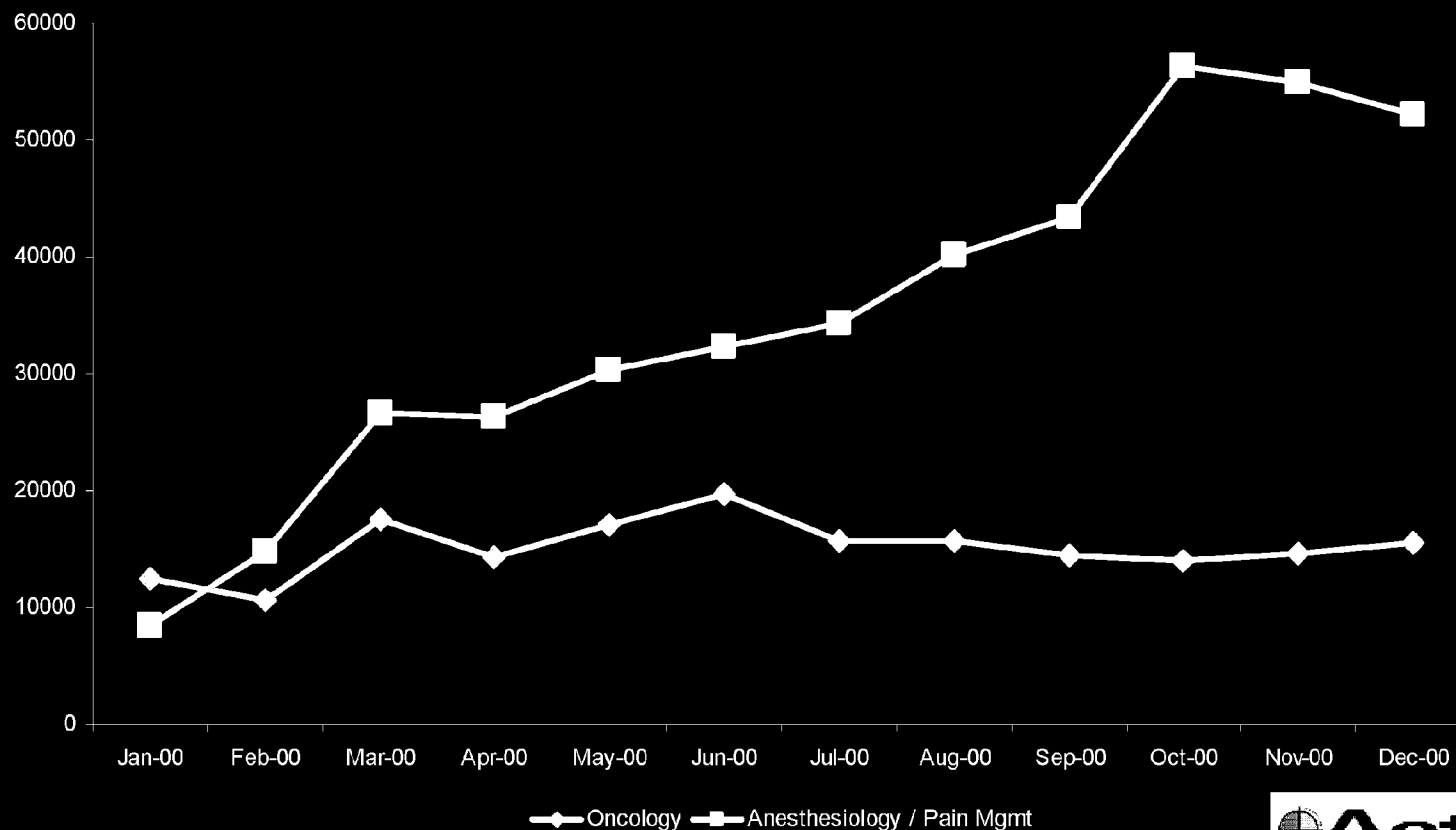


# Xponent – Monthly TRx by Specialty





# Xponent – Monthly Units by Specialty



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(oral transmucosal  
fentanyl citrate)

# Where are your \$\$ coming from?

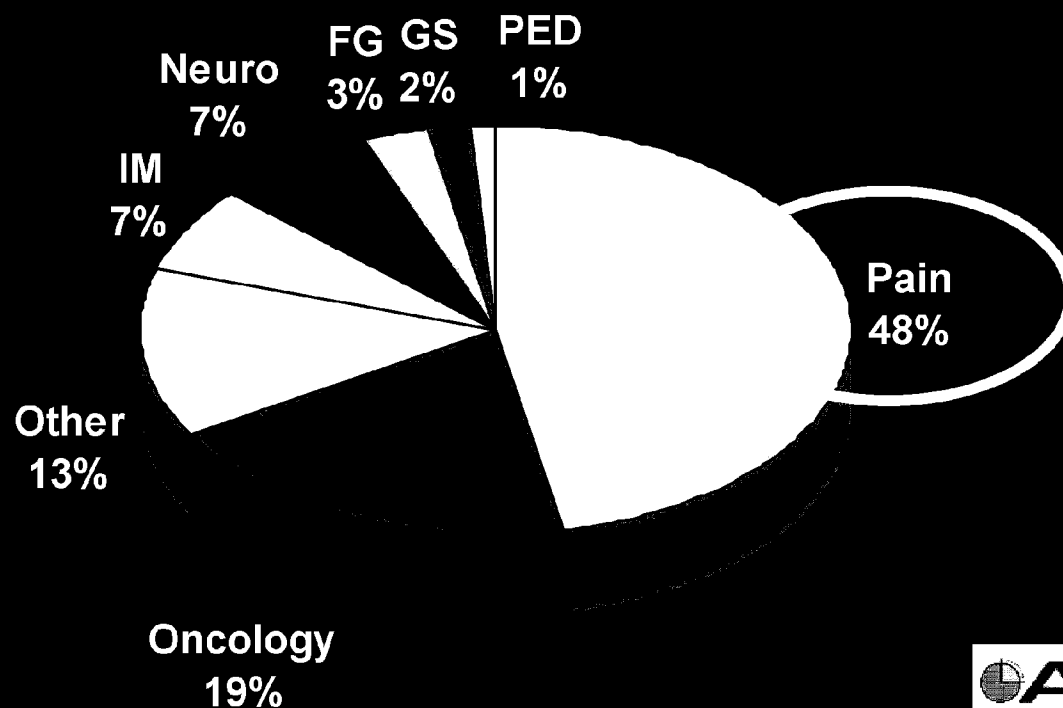
- Oncologists account for:
  - 1 of 4 scripts
  - 1 of 5 units
  - 1 of 6 \$\$
- Pain Specialists / Anesthesiologists
  - Account for 2 of 5 scripts/units/\$\$
- Pain / Anes, Neurology and “Other” all growing at a faster rate than Oncology
- Targeting, Targeting, Targeting



# Actiq Decile Analysis

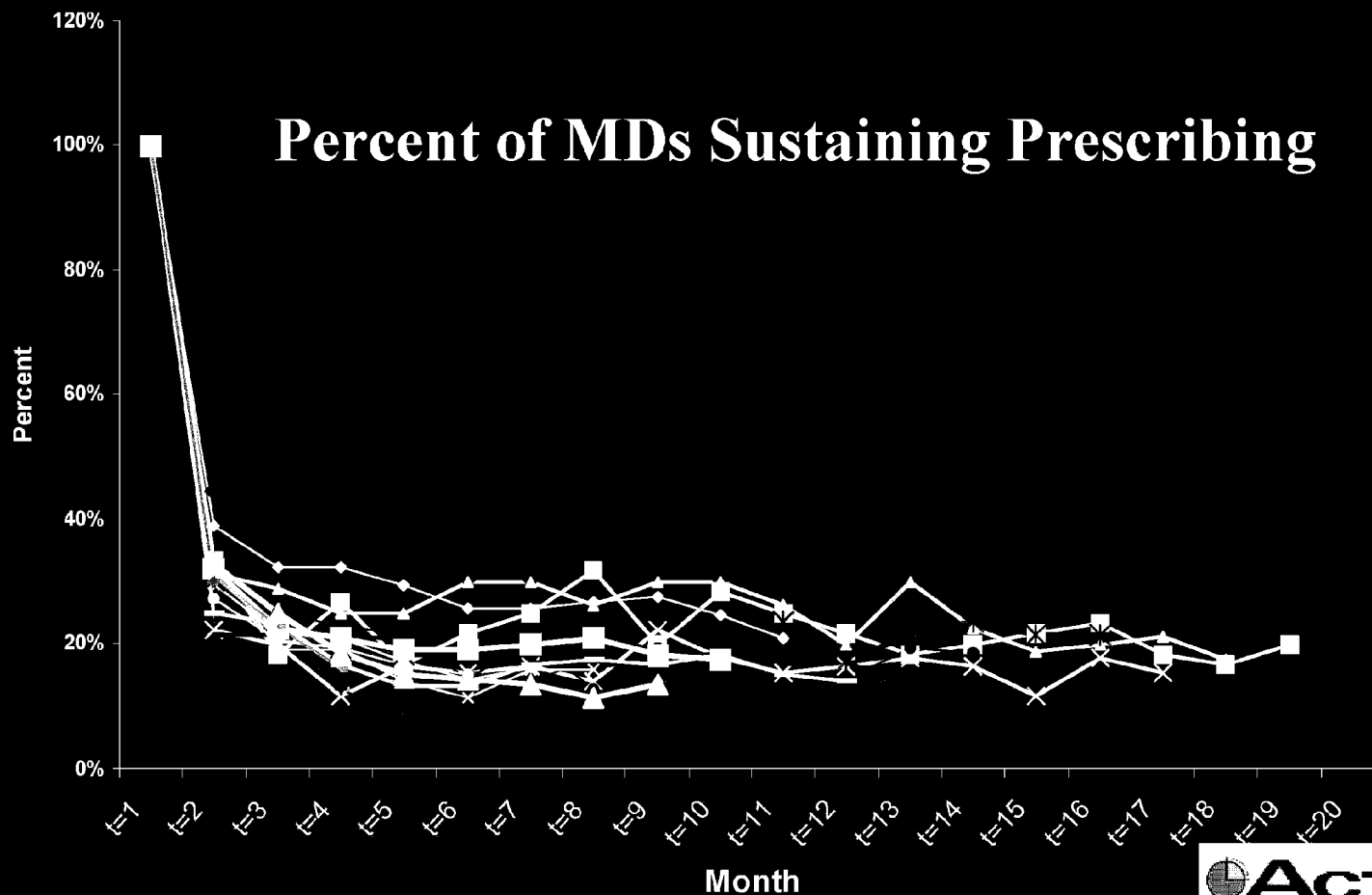
## Xponent – Physician Prescribers

Top Five Decile Prescribers YTD - Nov 2000  
(n=98)



**Actiq**<sup>®</sup>  
(oral transmucosal  
fentanyl citrate)

# Actiq Prescriber Retention Rate



# Prescriber Retention Research

Performed in February 2000

## Results:

- Efficacy not questioned
  - Lead product “like” – rapid onset
- Factors limiting use
  - Lead product “dislikes” – titration, cost
  - Reimbursement and availability hassles
  - Difficult to change prescribing habits



# Market Drivers

<u>Market Drivers</u>	<u>Jan 2000</u>	<u>Dec 2000</u>	<u>Trend</u>
TRx	864	2,534	↑
RX Size	38 units/ RX	55 units/ RX	↑
Average Selling Price	\$8.01	\$10.03	↑
Total Prescribers	282	636	↑
Units/ MD	129	210	↑
Average Retention Rate	21%		



# IV. Key Issues, Strategies and Tactics



# Key Marketing Issues

1. Lack of meaningful, focused positioning and message
2. Low awareness of Actiq due to limited promotional support
3. Logistical barriers to product adoption that restrict access and prescribing
4. Lack of knowledge about BTP and Actiq
5. Prescriber retention





# 1. ISSUE: Lack of meaningful, focused positioning and message

- Minimal advertising
- Poor initial concepts (“iceberg” and “unit”)
  - “Iceberg” and “Unit” concepts
    - Focused on BTP and delivery system only
    - Lacked features & benefits
    - Did not provide meaningful reason to prescribe



# “Iceberg” Concept



**Actiq<sup>®</sup>**  
(oral transmucosal  
fentanyl citrate)

# “Unit” Concept

## NOW AVAILABLE

A DELIVERY  
SYSTEM DESIGNED TO MAKE  
A DIFFERENCE

Breakthrough oral transmucosal delivery

**Actiq<sup>®</sup>** (oral transmucosal  
fentanyl citrate)



### Important Warnings

- Only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.
- Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, Actiq is contraindicated in the management of acute or postoperative pain.
- This product must not be used in opioid non-tolerant patients.
- Instruct patients/caregivers Actiq can be fatal to a child. Keep open units from children and discard properly.

See boxed warning and full prescribing information on following pages.

Actiq is a registered trademark of Amgen Corp.



Amgen Laboratories Inc.  
Molecular Products Division  
Molecular Products, Inc. 20000 11th  
1 800 438 0771

**Actiq<sup>®</sup>**  
(oral transmucosal  
fentanyl citrate)

# 1. ISSUE: Lack of meaningful, focused positioning and message

## STRATEGY

- Re-launch Actiq with revised branding and positioning that provides a meaningful, focused positioning and message



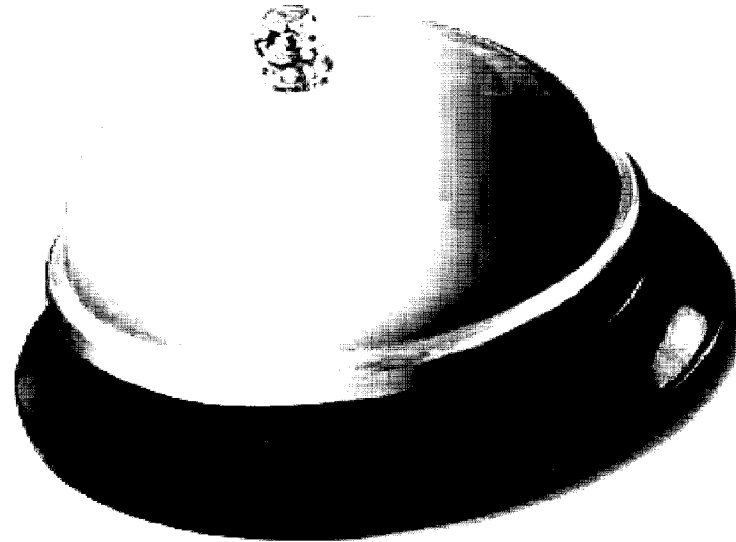
# 1. ISSUE: Lack of meaningful, focused positioning and message

## TACTIC

- New Concept developed (“Bell”)
  - Tested among Oncologists and APMs
  - Provides two key messages and a meaningful reason to prescribe
    - “Bell” and “Relief on demand” convey
      1. Rapid onset
      2. Personal pain control
- Awaiting FDA approval



B R E A K T H R O U G H C A N C E R P A I N



Relief on demand.



## 2. ISSUE: Low awareness

- Limited promotional support
  - Limited field presence for initial 1999 launch (20 reps)
  - Lack of presence at major conventions
  - Lack of advertising in professional journals
  - No direct mail to physicians to support field efforts
  - Limited \$\$ for MEPs
  - Limited \$\$ for CME programs



## 2. ISSUE: Low awareness

### STRATEGY

- Improve / Increase direct promotional reach and frequency
- Establish indirect and semi-direct promotional efforts





## 2. ISSUE: Low awareness

### TACTICS

- Upgrade field personnel and refine target audience
- Establish a presence at major conventions
  - Conventions we will have a presence at THIS year:
    - American Academy of Pain Medicine (Feb)
    - American Pain Society (April)
    - American Society of Clinical Oncology (May)
    - Oncology Nursing Society (May)
    - American Academy of Pain Management (Sept)
    - American Society of Anesthesiology (Oct)
  - MLs to provide additional presence at regional meetings



A new  
standard bearer in  
the evolving world of pain  
management.



## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- Media Plan (journal advertisements)
  - May books targeted
  - Professional Journals we will advertise in THIS year:
    - Journal of Clinical Oncology
    - Oncology
    - Oncology Times
    - Oncology Nurses Forum
    - Journal of Pain
    - Journal of Pain and Symptom Management
    - Pain Medicine
    - Pain Digest



Relief on demand.



As a result, the model is able to capture the temporal dependencies between the input and output sequences. The model is trained using a loss function that measures the difference between the predicted and target sequences. The model is evaluated using a validation set to ensure that it generalizes well to new data. The model is implemented using the PyTorch framework.

## ▼ Important Warnings

- *Only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.*
  - ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opioids.
  - This product must not be used in opioid non-tolerant patients.
  - Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep open units from children and discard properly.
- Please see brief warning and brief summary of prescribing information on following pages.
- [www.actiq.com](http://www.actiq.com)

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(oral transmucosal  
fentanyl citrate)

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CEP TPP CTAG10064778

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**Confidential**

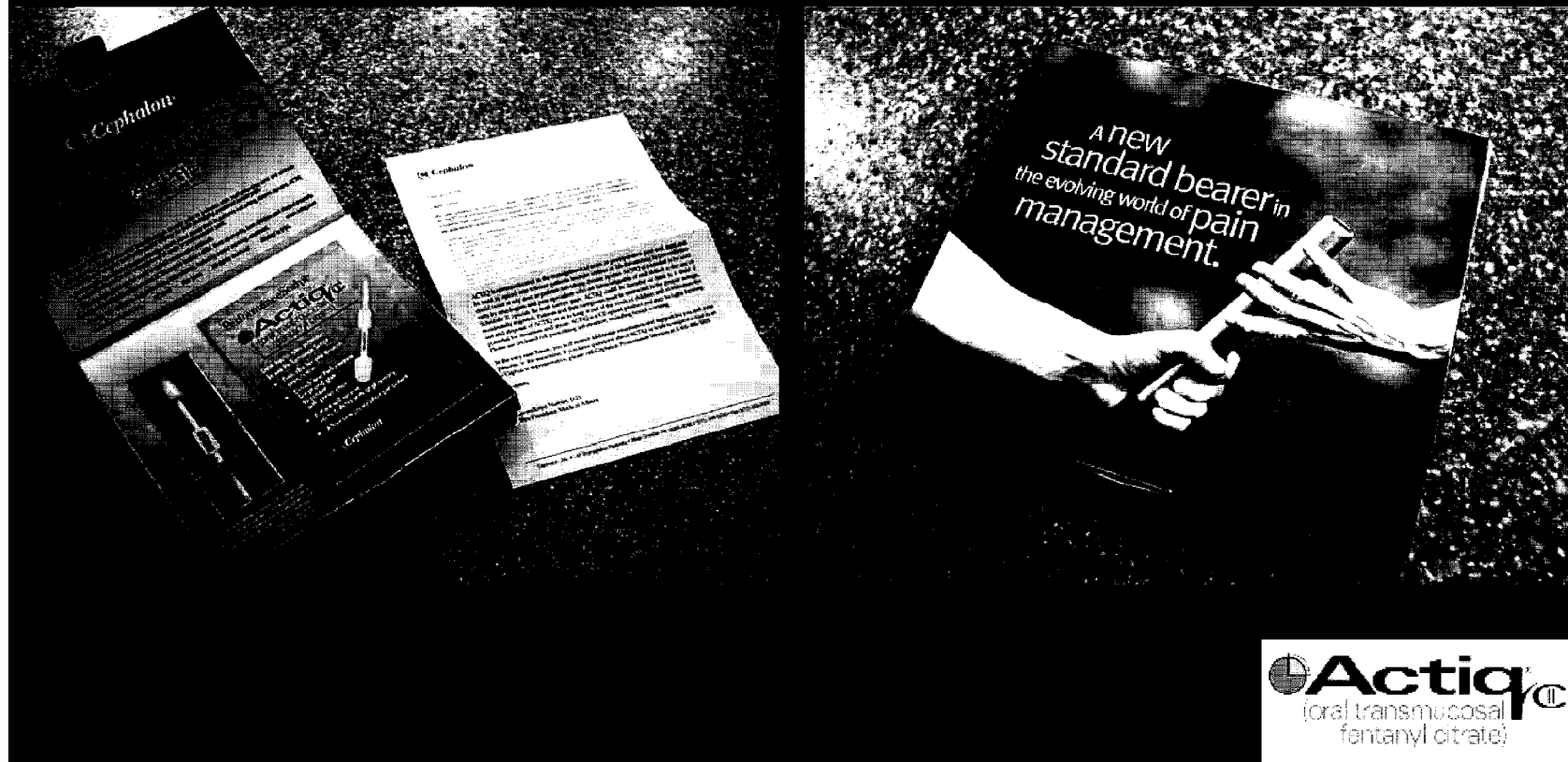
## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- Website upgrade
  - Targeted for May / June
- Direct Mail Campaign
  - First mailing targeted for April
  - Two additional mailings (June and Sept)



# March 2001 Direct Mail Effort



## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- Enhance speaker advocacy and expand speakers bureau
  - Develop extranet site (targeted for April / May)
  - Two Regional Consultants meetings planned for June
- Increase MEP activity
  - Big \$\$ driving these programs
  - Must maximize impact (ROI)
  - Right: audience / message / speaker / format



## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- Increase CME activity
  - Promoted through direct mailings and sales force





## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- Teletopics
  - Dr. James Cleary - “New Algorithms for Pain Management”
    - Dates in May, June, Sept, Oct
  - Content adapted to CD ROM for CME self-study
- “Profiles in Pain Management”
  - Quarterly newsletter / CD ROM self-study
  - Current hot topics / case studies / reprints



## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- Regional Symposia
  - Targeted for Fall 2001
  - Targeting 3 metropolitan areas
    - If successful, may expand sites
  - Topics to be identified and may include:
    - MSIR v. Actiq study
    - Dr. Forest Tennant Survey Research
  - Content will be adapted to:
    - CD ROM self-study
    - Teleconferences



## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- “A Nurse’s Guide to Breakthrough Pain”
  - Distributed through 3<sup>rd</sup> party to ONS and AAPMNS members
- Four page write-up of Dr. Forest Tennant’s Survey Research
  - Presented at the AAPM National Conference in February 2001



## 2. ISSUE: Low awareness

### TACTICS (cont'd)

- CME Library
  - ProfilesinPainManagement.com
  - Online self-study
    - Accessible 24/7
    - Every adapted CME program will be accessible
- Other CE programs to be developed



### 3. ISSUE: Logistical barriers

- Wholesalers not adequately stocked at various points during 2000
- Retail pharmacies reluctant to stock
- Insufficient and inconsistent reimbursement



### 3. ISSUE: Logistical barriers

#### STRATEGY

- Maintain appropriate wholesaler inventories
- Market research to identify problems / trends in retail pharmacies
- Facilitate reimbursement



### 3. ISSUE: Logistical barriers

#### TACTICS

- Distribution and Logistics Department
  - Ensuring wholesalers are adequately stocked through new / improved relationships
  - New distribution warehouse (DDN) ensures rapid shipment of product to wholesalers
    - 2 day turnaround (versus 2-3 weeks prior)
  - Identifying options to secure product availability at retail pharmacies



### 3. ISSUE: Logistical barriers

#### TACTICS (cont'd)

- Market research to identify problems / trends in retail pharmacies (completed Jan 2001)
  - Surveyed 201 retail pharmacies
    - 99 independent / small chain; 102 large chain
  - Results:
    - 7% reported stocking Actiq; no difference b/w pharmacy types
    - Non-stocking pharmacies
      - 65% reported “no scripts” as primary reason
      - 35% reported being “not aware” as primary reason
  - Conclusion:
    - Retail pharmacies will stock as demand increases and awareness improves





### 3. ISSUE: Logistical barriers

#### TACTICS (cont'd)

- Identified new vendor for PAP / Reimbursement Program
  - Pracon replaces CRC
  - Will assume responsibilities March 2001
    - Details in workshop
  - Accessible through Cephalon Professional Services line (800-896-5855)
  - PAP will only support patients with malignancies
  - Reimbursement Program will support all patients



## 4. ISSUE: Lack of knowledge

- BTP not well understood
- Pain management not primary concern of Oncologists
- Misperceptions about cost of Actiq
- Poor understanding of the relative potency of Actiq



## 4. ISSUE: Lack of knowledge

### STRATEGY

- Create advocacy among key thought leaders
- Educate clinicians about BTP and Actiq
- Support aggressive treatment of BTP with key pain associations via PR efforts



## 4. ISSUE: Lack of knowledge

### TACTICS

- MLs (and PCSs) to develop Actiq speaker bureau
- CME programs to assist in clinician education (previously listed)



## 4. ISSUE: Lack of knowledge

### TACTICS (cont'd)

- Medical Education Programs
  - Discovery International to assist in coordination
  - Minimum 5 per territory (240 total MEPs)
  - Topics for MEPs
    - Effective Management of BTCP
    - Effective Management of BTP in Patients with Metastatic Bone Pain
    - Management of BTP in the Difficult Radiation Patient
    - Management of BTP in the New JCAHO Standards

